

CLAIMS

1. An implantable drug delivery system, comprising:
- an infusion pump including a fluid outlet;
- 5 a fluid delivery pathway effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site; and
- a controlled release drug assembly, said drug assembly being configured for controllably releasing drug material, and communicating with said fluid delivery pathway such that the drug material is released into said
- 10 fluid delivery pathway,
- wherein the pump assembly is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the fluid pathway discharges at the discharge portion to treat the target tissue site.
- 15 2. The system of claim 1, wherein the pump further comprises a power source.
3. The system of claim 1, wherein the pump includes a chamber for holding a predetermined quantity of carrier fluid.
- 20 4. The system of claim 1, further comprising a chamber having a concentrated delivery agent, and configured to release the delivery agent into carrier fluid.
5. The system of claim 1, further comprising a mixing chamber operative to mix a drug or delivery agent in carrier fluid.
- 25 6. The system of claim 1, wherein the pump further includes an inlet pathway for delivering said carrier fluid to the pump, said pump being effective to convey the fluid from the inlet to the outlet.
- 30 7. The system of claim 1, wherein the controlled release drug assembly is a microchip having at least one drug reservoir, and wherein the microchip is in fluid communication with the fluid delivery pathway intermediate to the pump and the target tissue site.

8. The system of claim 7, wherein the microchip is located in the fluid delivery pathway.

5 9. The system of claim 1, wherein the controlled release drug assembly is located outside the fluid delivery pathway.

10 10. The system of claim 1, wherein the carrier fluid is a fluid selected from the group consisting of a physiological buffer, a pharmaceutical excipient or adjuvant, an endogenous fluid, and combinations thereof.

11 11. The system of claim 10, wherein the carrier fluid is an endogenous fluid selected from the group consisting of cerebral spinal fluid, blood, lymphatic fluid, components thereof, and combinations thereof.

15 12. The system of claim 6, wherein the inlet pathway includes a separate catheter positionable in tissue for delivering an endogenous fluid to the pump.

20 13. The system of claim 12, wherein the separate catheter, the pump and the fluid delivery pathway are dimensioned for positioning in tissue to form an endogenous fluid circulation loop.

25 14. The system of claim 1, wherein the infusion pump includes a microcontrol unit that controls flow rate of the pump.

15. The system of claim 1, wherein the infusion pump is effective to pump at a rate to drive convection-enhanced transport into the target tissue site, thereby enhancing effective delivery profile at the target site.

30 16. The system of claim 1, wherein the flow rate ranges from about 0.5 to about 20 microliters per minute.

17. The system of claim 1, wherein the pump assembly includes a pump assembly selected from among the group consisting of a pressurized reservoir, a peristaltic pump, a diaphragm pump, and a piston pump.

5 18. The system of claim 12, wherein the separate catheter is configured to collect endogenous fluid from a donor site selected from the group of sites consisting of the central nervous system, the circulatory system and the lymphatic system.

10 19. The system of claim 1, wherein the drug release assembly includes a microchip powered by a power source.

20. The system of claim 14, wherein the microchip is in communication with the microcontrol unit.

15 21. The system of claim 12, wherein the controlled release drug assembly includes a microchip having a microprocessor that is in communication with the microcontrol unit.

20 22. The system of claim 1, wherein the drug release assembly includes a microchip containing one or more drugs therein.

25 23. The system of claim 22, wherein the drug release assembly includes a reservoir having a cap positioned over a drug contained therein, wherein release of the drug is controlled by diffusion through or disintegration of the cap.

24. The system of claim 23, wherein the drug release assembly includes a microchip having a microprocessor/controller, and diffusion through or disintegration of the cap is controlled by the microprocessor/controller.

30 25. The system of claim 1, wherein the drug release assembly is a microchip having a plurality of reservoirs containing plural different drugs, drug concentrations, or a combination thereof.

26. The system of claim 1 further comprising one or more biosensors, and wherein the system responds to a biosensor signal.

27. The system of claim 1, wherein the drug release assembly includes plural
5 controllable release sites positioned within a wall of the fluid delivery pathway.

28. The system of claim 1 further comprising an array of biosensors disposed in tissue, and wherein at least one of the infusion pump and the controlled drug release assembly responds to biosensor signals from the array.

10 29. A method for infusing a drug into a target tissue site of a subject, the method comprising the steps of:

providing an infusion pump assembly, wherein the pump assembly includes a carrier fluid source, wherein the infusion pump assembly is effective to convey a fluid
15 within the pump through a fluid delivery pathway to a target tissue site;

providing a drug release assembly in communication with the fluid delivery pathway, said release assembly having at least one drug reservoir configured for controlled release of a drug into the fluid delivery pathway; and

enabling a carrier fluid to be delivered under pressure from the infusion pump
20 assembly at a desired flow rate through the fluid delivery pathway to transport drug released by the drug release assembly to the target tissue site.

30. The method of claim 29, wherein the pump assembly is effective to deliver carrier fluid at a rate effective to induce convective bulk transport of the drug into
25 tissue at the target site.

31. The method of claim 30, wherein the target site is brain tissue and the pump assembly is effective to deliver carrier fluid at a rate in the range of about 0.5 to about 20 microliters/minute to induce convective bulk transport of the drug into brain tissue.

32. The method of claim 29, wherein the fluid delivery pathway terminates in a distal end, wherein the distal end is implantable within the target site.

33. The method of claim 29, wherein the one or more drugs are released in a delivery regimen selected from among a pulsatile, an intermittent and a continuous delivery regimen.

5 34. The method of claim 29, further including the step of providing a biosensor in at least one of the fluid delivery pathway, the tissue site and the controlled release assembly, and controlling at least one of the infusion pump assembly and the drug release assembly in response to biosensor signals.

10 35. The method of claim 29, further including the step of detecting a material or condition with a biosensor array, and controlling at least one of the infusion pump assembly and the drug release assembly in response thereto.

36. The method of claim 29, wherein the carrier fluid is selected from the group
15 consisting of a physiological buffer, a pharmaceutical excipient or adjuvant, an endogenous fluid, and combinations thereof.

37. The method of claim 29, wherein the carrier is an endogenous fluid selected from the group consisting of cerebral spinal fluid, blood, lymphatic fluid, components
20 thereof, and combinations thereof.

38. The method of claim 29, wherein the infusion pump assembly is operable to continuously maintain enhanced fluid pressure over a predetermined period of time.

25 39. The method of claim 29, wherein a microcontrol unit disposed within the infusion pump controls fluid delivery pressure profile over a predetermined period of time.

40. A method of delivering a drug or bioactive material to target tissue such as
30 tissue of the central nervous system (CNS), such method comprising the steps of providing an infusion pump having an output connectable with a delivery line implantable at a target tissue site; and

providing a controlled release drug device attachable in communication with the delivery line, such that the controlled release drug device is effective to release drug into carrier fluid pumped by the infusion pump;

- 5 thereby delivering the carrier fluid to the target tissue site with said drug, the pump being controllable to maintain an elevated delivery pressure such that the drug achieves a convectively enhanced profile in tissue at the target tissue site.